

D R A F T

**CONTROLLED SUBSTANCES BOARD
MADISON, WI
FEBRUARY 5, 2003**

PRESENT: Yvonne Bellay, Cynthia Benning, Douglas Englebert, Robert Sloey

EXCUSED: Kenneth Robbins, Thomas Rudy

STAFF PRESENT: Deanna Zychowski, Grace Schwingel

GUESTS: R. Martin Smith, Robert Block, Lucy Mormann, and Casey Collins – Crime Lab, DOJ;
David Buck – Professional Manufacturers Association (PMA)
Tony Driessen – American Chemical Council (ACC); Thomas Hill, and Patrick Braatz

CALL TO ORDER

Cynthia Benning, Chair, called the meeting to order at 9:30 a.m. A quorum of 4 members was present.

AGENDA

Amendments to Agenda:

Move item I to be discussed after item E to accommodate Yvonne Bellay's schedule.

A discussion on GHB will be discussed after item C.

MOTION: Robert Sloey moved, seconded by Yvonne Bellay, to approve the agenda as published. Motion carried unanimously.

ELECTION OF OFFICERS

MOTION: Robert Sloey moved, seconded by Yvonne Bellay, to elect Cynthia Benning as Chair. Motion carried unanimously.

MOTION: Yvonne Bellay moved, seconded by Robert Sloey, to elect Thomas Rudy as Vice Chair. Motion carried unanimously.

The Board has no documents that require a Secretary's signature, so the Board did not elect a Secretary.

NEW BOARD MEMBER – DOUG ENGLEBERT, R.PH.

Cynthia Benning introduced Doug Englebert, R.Ph. to the Board. Doug Englebert is the DHFS designated Representative member of the Board and is replacing Roma Rowlands on the Board. Doug is a Pharmacy Practice Consultant in the Bureau of Quality Assurance, which regulates licensed health care facilities such as hospitals, home health, nursing homes, etc. Doug trains all the surveyors for the state on the pharmacy aspects of what they need to be looking for when inspecting health care facilities.

APPROVAL OF MINUTES OF DECEMBER 4, 2002

Amendments: On page 3 of the minutes, under Report of NASCSA Meeting, change the name of the report to “National Forensics Laboratory Information System Quarterly Report.” On page 4 of the minutes, under Scott Zimmerman, change the first sentence to read: “. . . to approve the special use authorization for 50 mls . . . “

MOTION: Robert Sloey moved, seconded by Yvonne Bellay, to approve the minutes of December 4, 2002 as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF JANUARY 14, 2003

Amendments: Legal Counsel, William Black, was not present as indicated on the first page of the minutes.

MOTION: Robert Sloey moved, seconded by Douglas Englebert, to approve the minutes of 1/14/03 as amended. Motion carried unanimously.

REVIEW OF PROPOSED RULE RELATING TO RESCHEDULING BUPRENORPHINE FROM SCHEDULE V TO SCHEDULE III

Cynthia Benning reviewed the proposed rule relating to rescheduling buprenorphine from Schedule V to Schedule III, to conform to the federal standard. There is no change in the language, only a change in the numbering system. The Board answered questions from guests attending the meeting.

MOTION: Doug Englebert moved, seconded by Robert Sloey, to send the rule to the Clearinghouse. Motion carried unanimously.

DISCUSSION OF GAMMA-HYDROXYBUTRIC ACID (GHB)

Board members requested that they receive their agenda packets earlier so they have more time to gather information on issues like GHB. The Board had a lengthy discussion on substances that are not considered analogs and stated that there will need to be a period of fact-finding as to whether GHB should be classified as an analog. At this time there is not consensus among qualified, professional people as to whether or not

GHB should be classified as an analog. It can be argued either way depending on the initial point of view. Currently in Wisconsin GHB and GBL are Schedule I substances.

Wisconsin law states that for a substance to be considered an analog, it must have similar chemical structure and a similar effect in the body. The Board will need to define the parameters of what is meant by the term “similar.” The Board will also need to define the intent of the analog law as well as whether a substance is to be considered an analog as far as the law is concerned or as far as its chemical makeup.

Tony Driessen offered to work with Legal Counsel, William Black, on changing the statutes in order to have the statutes accurately reflect the original intent of the analog law. The need for industrial exemptions was also discussed. It was noted that federally GHB is considered an analog and the matter has been prosecuted successfully in MN as such, though there is not consistency among the states as to how GHB is classified.

The federal takes a two-pronged approach to this issue. The first aspect it considers is whether the substance is considered for human consumption. The second prong considered on the federal level is a) if the substance has a chemical structure that is substantially “similar” to Schedule I or Schedule II substances, or (b) does the substance create an effect in the human body that is substantially “similar” to the effect created by either a Schedule I or Schedule II substance, or, (c) has the substance been represented to be in Schedule I or Schedule II.

The Board will need to contact the FDA for appropriate language to use with regard to the use of GBL in the manufacturing process for making beer and wine.

Cynthia Benning sought assistance from each of the groups represented as guests at the Board’s meeting today – the Department of Justice Crime Lab, the American Chemical Council (ACC), and Professional Manufacturers Association (PMA), and requested that they submit a written opinion of the data they have and their perspective on this issue.

REVIEW OF MEDICAID DATA ON SELECTED CONTROLLED SUBSTANCES

For informational purposes

VETERINARY BOARD RESPONSE TO WILDLIFE RESEARCHERS AND REHABBERS SPECIAL USE PERMITS

Yvonne Bellay reported on the Vet Board’s discussion with response to wildlife researchers and rehabbers special use permits. It was noted that the consensus reached by the Vet Board, was that by statutory language, the permit that was issued by the CSB Board for the use of controlled substances, by a wildlife research group, to sedate wild animals for translocation, does not constitute the practice of veterinary medicine.

Because there are some gray areas that exist with regard to the use of controlled substances by veterinarians and researchers, the Board would like to get an understanding

of the position of the DEA regarding the issuance of sua's by the CSB Board before responding to the letter from the Veterinary Board.

REVIEW OF SUA APPLICATION AND INSTRUCTION SHEET – KRIS HENDRICKSON

Kris Hendrickson introduced herself and explained the role she plays in the Department with regard to her work with the Boards and the handling of the SUA applications. Kris Hendrickson has a new position as Credentialing Supervisor; she licenses pharmacies, distributors, manufacturers, and pharmacists.

In an effort to improve efficiency in the Department's process for handling applications, and to better meet the needs of applicants, Kris Hendrickson reviewed recommended revisions to the Department's instruction and application forms used by the Controlled Substances Board. The Board would like to include a DEA warning and to convey to sua applicants on the renewal form that they are in violation of their authorization if they have quantities of controlled substances in their possession in excess of the amount indicated on their sua form.

MOTION: Robert Sloey moved, seconded by Doug Englebert, to authorize Cynthia Benning to work with Legal Counsel, William Black, and Kris Hendrickson, to finalize the language for the letter sent with the renewal form. Motion carried unanimously.

Yvonne Bellay left the meeting at 10:45 a.m. which left the Board without a quorum. The Board agreed to have a teleconference call on Thursday, February 20, 2003 at 9:00 a.m. to approve SUA's and other Board licenses.

ADJOURNMENT

MOTION: Robert Sloey moved, seconded by Doug Englebert, to adjourn the meeting at 10:45 a.m. as there was no longer a quorum of the Board members present. Motion carried unanimously.

Next Meeting: April 2, 2003